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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,159

01/20/2004

Biten K. Kathrani

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2562

27777 7590 01/23/2009
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,159	Applicant(s) KATHRANI ET AL.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 28-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 28-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28, 30, 32-36, and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorsey, III (5,505,710). Dorsey discloses an assembly comprising a vacuum device (not shown, the assembly is designed for irrigation and suction and therefore inherently has a vacuum device) sized and shaped to be positioned against a portion of a patient's body (any vacuum device is capable of being positioned against a portion of a patient's body) wherein the vacuum device can provide an operative space within a patient, and a multi-component device capable of providing access from a point external of the vacuum device to a point within a patient, the device comprising detachable first (12,127,227, etc.) and second (13,160,260) members for providing access passageways, wherein the first member has an open distal tip, a pointed tip (254) selected from the group consisting of bifurcated and non-bifurcated, further comprising a cap (14, 114, 214) releasably attachable to the proximal end of the first and second members, wherein the tip (254) is capable of piercing a perforable membrane, wherein the first member includes openings (28) through the sidewall, wherein the second member includes openings (264) through the sidewall, and further

Art Unit: 3763

comprising a sleeve (30,130,230) positionable along an outside surface of the first member.

Claims 26, 28, 30, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama (3,896,810). Akiyama discloses an assembly comprising a vacuum device (28, 32) sized and shaped to be positioned against a portion of a patient's body (any vacuum device is capable of being positioned against a portion of a patient's body) wherein the vacuum device can provide an operative space within a patient, and a multi-component device capable of providing access from a point external of the vacuum device to a point within a patient, the device comprising detachable first (15) and second (10) members for providing access passageways, wherein the first member has an open distal tip, a pointed tip (22) selected from the group consisting of bifurcated and non-bifurcated, and wherein the tip (22) is capable of piercing a perforable membrane.

Claims 26, 29, 31-35, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by McIntyre (4,014,333). McIntyre discloses an assembly comprising a vacuum device (11) sized and shaped to be positioned against a portion of a patient's body (any vacuum device is capable of being positioned against a portion of a patient's body) wherein the vacuum device can provide an operative space within a patient, and a multi-component device capable of providing access from a point external of the vacuum device to a point within a patient, the device comprising detachable first (1) and second (4) members for providing access passageways, wherein the first member has a closed distal tip, wherein the first member has a relatively rigid body portion (3) and a

Art Unit: 3763

relatively flexible distal end portion (8), further comprising a cap (19) releasably attachable to the proximal end of the first and second members, wherein the tip is capable of piercing a perforable membrane, wherein the first member includes an opening (16) through the sidewall, wherein the second member includes openings (15) through the sidewall, and wherein the second member includes a beveled distal end.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III (5,505,710), Akiyama, and McIntyre (4,014,333). The references disclose the claimed invention except for the use of transparent material and a non-circular cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use transparent material and a non-circular cross section, since it has been held to be within the general skill of a worker in the art to select a

Art Unit: 3763

known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) and a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Response to Arguments

Applicant's arguments filed 10/23/2008 have been fully considered but they are not persuasive.

In response to the applicant's argument that the references do not disclose a vacuum device sized and shaped to be positioned against a portion of the patient's body, the examiner respectfully disagrees. This limitation is interpreted as a functional limitation of which the vacuum devices in the cited art are capable of performing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3763

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Application/Control Number: 10/761,159
Art Unit: 3763

Page 7